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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/053,088 | 01/18/2002 | Graham John Hamilton Melrose | 2354/141 (FF34527/02) | 6479 |

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| EXAMINER | |
|---|---|
| KUMAR, PREETI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1751 | |

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/053,088 | MELROSE ET AL. | |
| | Examiner | Art Unit | |
| | Preeti Kumar | 1751 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-13,15-17,24-42 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,15-17,24-42 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to After-Final Amendment*

1. The After-Final Amendment filed 1/30/2006 has been entered.

2. Claims 2-13, 15-17, 24-42, 44-47 are pending.

3. Ex Parte Prosecution on the merits of this application is re-opened on claims 2-13, 15-17, 24-42, 44-47 upon further consideration of the prior art.

4. The rejection of claims 1-9 and 11-23 and 43-47 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 00/03723) is withdrawn upon further consideration of the prior art date.

5. The rejection of claims 29 under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (WO 00/03723) is withdrawn upon further review of the prior art.

6. The rejection of claims 24-28 and 30-42 under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (WO 00/03723) is maintained for the reasons recited in the previous office action and further explained under the new grounds of rejection.

### *Response to Arguments*

7. Applicant's arguments, filed 1/30/2006, with respect to the rejection(s)of 2-13, 15-17, 24-42, 44-47 have been fully considered. However, upon further consideration of the prior art, a new ground(s) of rejection is made below.

### *New Grounds of Rejection*

### *Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 2-13, 15-17, and 44-47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 00/03723).

Melrose et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) comprising the method steps of dissolving the poly(2-propenal, 2-propenoic acid) in aqueous base, adding an organic compound containing one or more hydrophobic groups, and subsequently acidifying the solution, whereby interaction between the hydrophobic groups of the organic compound and the poly(2-propenal, 2-propenoic acid) prevents precipitation of the poly(2-propenal, 2-propenoic acid) occurring at pH >5.5 and the solution is consequently stable over a broad pH range. See abstract. Specifically, Melrose et al. teach polymeric compounds having a polyacrolein sub-unit in aldehyde, hydrated, hemi-acetal or acetal form and having biostatic or biocidal properties and the biostatic and/or biocidal uses of these compositions. See page 2, ln.10-25.

Melrose et al. teach that antimicrobial compositions may be used as preservatives, or as the active ingredients in disinfectants, dermatological compositions including sun screen formulations or antiseptic formulations, or in animal feed additives. Generally these antimicrobial compositions must: be stable; be efficacious in killing

micro-organisms within a specified time; be safe, that is be reasonably free of toxicity which may be caused by the trans-dermal migration of low molecular weight ingredients into the blood-stream so as to manifest toxicity, antigenicity, allergy, irritation or inflammation; have minimal odor; and in some dermatological preparations, have the property of sun screening and minimize adverse dermatological effects from the generation of free-radicals. See pages 2-3.

Specifically regarding claims 12-13 and 15-17, Melrose et al. teach that the composition further comprises one or more of ethylene diamine tetra acetic acid, a lower alkanol, a phenol, isothiazolinones and glutaraldehyde, whereby the composition exhibits a synergistic increase in antimicrobial activity. See page 5 and example 7, page 17. In example 5 on page 16, Melrose et al. illustrate in formulation a) a composition comprising 1.5% antimicrobial polymer in 65% ethanol. See line 8 of pg.16.

Regarding claims 44-47, Melrose et al. teach the utility of a composition comprising poly(2-propenal, 2-propenoic acid) and polyethylene glycol as an animal feed additive. See abstract and page 4,lines 1-9.

Melrose et al. illustrate in example 1, that the antimicrobial composition is combined with an anticancer agent such as hydroquinone. See page 12,ln.20-25.

Melrose et al. illustrate microbiological test of poly(2-propenal, 2-propenoic acid) to kill various organisms such as P. vulgaris, E. coli, and Ps. Aeruginosa which cause gastrointestinal disease in animals. See Table 10A, page 23.

Melrose et al. illustrate in example 8 the effects of the presence of poly(2-propenal, 2-propenoic acid) on the migration of various agents across a model for skin wherein (a) poly(2-propenal, 2-propenoic acid) (0.5 g) was dissolved in polyethylene glycol 1000 (10 g) by stirring at 70 C., then sodium hydroxide micro-pellets (50 mg) were added and stirred for 2 minutes, and then octyl methoxy cinnimate (10 g; sunscreen agent) was added, followed by a mixture of the polymeric emulsifiers PEMULIN TR1 and CARBOPOL 2984 (0.5 g; equal parts) whilst maintaining the temperature at 70 C./15 minutes. See page 19.

Melrose et al. illustrates a composition comprising poly(2-propenal, 2-propenoic acid) in polyethylene glycol which is substantially identical to the material limitations of the instant claims. Accordingly, the teachings of Melrose et al. anticipate the material limitations of the instant claims.

Alternatively, even if the broad teachings of Melrose et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an antimicrobial composition comprising a derivative of poly(2-propenal, 2-propenoic acid) in polyethylene glycol having protected carbonyl groups and reduction of $H^1$NMR signal as recited by the instant claims, because Melrose et al. teach a reaction of poly(2-propenal, 2-propenoic acid) and polyethylene glycol for 15 minutes at 70 degrees C. See example 8 (a) page 19. Furthermore, limitations to protected carbonyl groups and reduction in $H^1$NMR signal are encompassed by the invention of Melrose et al. because Melrose et al. illustrate by example the use of similar materials (i.e. poly(2-propenal, 2-propenoic

acid)) and in the similar production steps (i.e. reaction with polyethylene glycol) to produce an antimicrobial composition which are useful preservatives, or as the active ingredients in disinfectants, dermatological compositions including sun screen formulations or antiseptic formulations, or in animal feed additives meeting regulatory standards. The same components in the same composition would result in the same property of $H^1$NMR signal reduction and the carbonyl groups being protected. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

11. Claims 24-28 and 30-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (WO 00/03723).

Melrose et al. are relied upon as set forth above.

Melrose et al. do not specifically teach a method of treating gastrointestinal disease in an animal with compositions of poly(2-propenal, 2-propenoic acid) and the specified dosages for administration as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the invention was mate to use a composition comprising poly(2-propenal, 2-propenoic acid) in a method of treating gastrointestinal diseases in animals as recited by the instant claims, with a reasonable expectation of success, because Melrose et al. suggest the use of poly(2-propenal, 2-propenoic acid) as an antimicrobial agent in animal feed to kill organisms such as P. vulgaris, E. coli, Ps. Aeruginosa which cause gastrointestinal disease in animals. See Table 10A, page 23 and page 4,lines 1-9. Also, one of ordinary skill in the art would have been motivated to modify the dosage of the antimicrobial

composition to achieve optimal kill ratio of the microbe(s) while maintaining the health of the animal.

12. Claims 2-11, and 44-45 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 00/01/60874).

Regarding claims 2-11, Melrose et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) comprising the method steps of dissolving the poly(2-propenal, 2-propenoic acid) in water or PEG 200. See Example 1 and 2 on page 8. Melrose et al. teach polymeric compounds having a polyacrolein sub-unit in aldehyde, hydrated, hemi-acetal or acetal form and having biostatic or biocidal properties and the biostatic and/or biocidal uses of these compositions. See page 1-2. In examples 2 and 8 on pages 8-9 and 15-16, Melrose et al. illustrate, the reaction of poly(2-propenal, 2-propenoic acid) with PEG 200. The resulting antimicrobial composition is utilized to kill microbes which cause gastrointestinal disease such as microbes originating from P. aeruginosa, S. aureus, and S. choleraesuis.

Melrose et al. illustrates a composition comprising poly(2-propenal, 2-propenoic acid) in polyethylene glycol which is substantially identical to the material limitations of the instant claims. Accordingly, the teachings of Melrose et al. anticipate the material limitations of the instant claims.

Alternatively, even if the broad teachings of Melrose et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an antimicrobial composition

comprising a derivative of poly(2-propenal, 2-propenoic acid) in polyethylene glycol having protected carbonyl groups and reduction of $H^1$NMR signal as recited by the instant claims, because Melrose et al. teach a reaction of poly(2-propenal, 2-propenoic acid) and polyethylene glycol for 12 or 25 days at 60 C. See example 2 page 9. Furthermore, limitations to protected carbonyl groups and reduction in $H^1$NMR signal are encompassed by the invention of Melrose et al. because Melrose et al. illustrate by example the use of similar materials (i.e. poly(2-propenal, 2-propenoic acid)) and in the similar production steps (i.e. reaction with polyethylene glycol) to produce an antimicrobial composition. The same components in the same composition would result in the same property of $H^1$NMR signal reduction and the carbonyl groups being protected. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

***Allowable Subject Matter***

13. Claim 29 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art made of record do not specifically teach the claimed method of rectally administering the antimicrobial composition to ruminant animals. The prior art suggests oral administration by combination to animal feed.

***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Mc Ginty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Preeti Kumar PK
Examiner
Art Unit 1751

PK

Douglas McGinty
Supervisory Patent Examiner
Art Unit 1751